WSIRB Review Presentation Guide

(online template: http://www1.dshs.wa.gov/rda/hrrs/handbook)

Brief summary of the study: (about 5 minutes or less)
Summarize the "who, what, why, when, where and how" of the study.

Review questions or concerns:
Regulatory review requirements to consider: scientific merit, subject selection/recruitment, vulnerable populations, informed consent process/documents, waivers/alterations of informed consent, privacy/confidentiality.

Risk/benefit analysis:
Identify potential benefits and risks. Discuss risk/benefit ratio. Ways to improve ratio?

Level of risk: ☐ Minimal Risk ☐ More than Minimal Risk

Waiver of consent/assent:
- ☐ Waive for some/all subjects
- ☐ Require consent/assent for some/all subjects
- ☐ Waive elements of informed consent/assent: _____

Waiver of documentation of consent/assent:
- ☐ Waive for some/all subjects
- ☐ Require consent/assent for some/all subjects
- ☐ Not applicable

Waiver of authorization:
- ☐ Waive for some/all subjects
- ☐ Require signed authorization from some/all subjects for disclosure of records
- ☐ Not applicable

Special protections:

Subpart B, Pregnant women/fetuses:

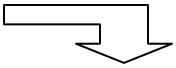
- ☐ Meets criteria in section ___
- ☐ Does not meet criteria
- ☐ Not applicable

Subpart C, Prisoners:

- ☐ Meets criteria in section 306, category ___
- ☐ Does not meet criteria in section 306
- ☐ Meets criteria for waiver of special protections
- ☐ Not applicable

Subpart D, Children:

- ☐ Meets criteria in section ___
- ☐ Does not meet criteria
- ☐ Not applicable



Parental Consent:

- ☐ Require, meets criteria in section ___
- ☐ Waive, meets criteria in section __
- ☐ Not applicable

Propose disposition recommendation:

☐ Approve as submitted

Recommended approval period: _____ (1 year maximum)

☐ Conditional approval

Recommended approval period: _____ (1 year maximum)

Approval Conditions:

☐ Defer

Review issues:

☐ Disapprove project

Review issues: